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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,795	05/28/2004	Michael A. Slivka	101896-252 (DEP5319)	3794
21125 7590 09/05/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 09/05/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/709,795	<b>Applicant(s)</b> SLIVKA ET AL.	
	<b>Examiner</b> Richard Shaffer	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-19, 21-27, 29-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 13-16 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/10/2008; 7/23/2008</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10<sup>th</sup>, 2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 7, 10-12, 17-19, 21, 22-24, 26, 27, 29-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (US Patent Application Publication 2004/0260284) in view of Biedermann et al (US Patent Application Publication 2004/0049190).

Parker discloses (**Figure 1**) a device comprising: a bone-engaging member (**105**) having a spherical head (**110**) formed thereon; a U-shaped receiver member (**115**); the receiver (**115**) having a proximal recess/seat (**155**) that receives a (rigid or flexible since it has to be one) spinal rod (**200**); a threaded (**150**) setscrew/fastener (**145**) to mate with the receiver to lock the spinal rod in position while allowing free polyaxial movement of

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the bone-engaging member (**105**); the bone-engaging member (**105**) has its head mated to a distal cavity (**112**) of the receiver.

Parker fails to disclose an opening extending between the proximal recess (**155**) and distal cavity (**112**) where the opening is sized to prevent passage of a spinal fixation element.

Biedermann et al teach (**Figures 3 and 4; Page 2, Paragraph 0027; and Page 3, Paragraph 0034**) that a passageway (**17**) too small to allow the spinal rod to pass is provided to allow a screw driver to engage the bone-engaging member. This allows the bone-engaging member to be pre-assembled to the U-shaped receiver member and ready to accept the spinal rod immediately after fixation in the bone without any intermediate steps thereby minimizing the complexity and duration of surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a small passageway between the proximal recess and distal cavity of Parker in order to allow for the components to be pre-assembled thereby reducing surgical complexity and duration.

Parker in view of Biedermann et al disclose and teach all of the claimed limitations except for the spinal fixation element being formed from a material from the group consisting of stainless steel, titanium, non-absorbable polymers, absorbable polymers, and combinations thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a material from applicant's group of appropriate materials since it has been held to be within the general skill of a worker in the art to select a

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known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 1, 6, 7, 10-12, 17-19, 21, 22-24, 26, 27, 29-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Errico et al (US Patent 5,690,630).

As described previously, Parker disclose all of the claimed limitations except for an opening extending between the proximal recess (**155**) and distal cavity (**112**) where the opening is sized to prevent passage of a spinal fixation element.

Errico et al teach (**Figure 8 and Column 8, Line 60 through Column 9, Line 15**) the use of a pre-assembled polyaxial screw system where a small bore (**155**) passing between the proximal recess and distal cavity is provided for driving the bone-engaging member. This reduces steps performed during surgery thereby reducing the complexity and duration of the procedure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a small passageway between the proximal recess and distal cavity of Parker in order to allow for the components to be pre-assembled thereby reducing surgical complexity and duration.

Parker in view of Errico et al disclose and teach all of the claimed limitations except for the spinal fixation element being formed from a material from the group consisting of stainless steel, titanium, non-absorbable polymers, absorbable polymers, and combinations thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a material from applicant's group of appropriate materials since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments filed on June 10<sup>th</sup>, 2008 have been fully considered but they are not persuasive. As addressed in the Advisory Action (in support of the Final Office Action mailed on December 10<sup>th</sup>, 2007) mailed on February 26<sup>th</sup>, 2008, it was stated that the teachings gleaned from Biedermann et al and Errico et al (both separate analyses) were that a small passageway accessing the head of the screw was important to minimize time and complexity of surgery. Therefore, it was taught that an opening in the pre-existing structure of Parker would be obvious and therefore such an opening would be "defined by the U-shaped receiver member." Applicant has added no additional limitation to change the previous analysis set forth in the Final Office Action mailed on December 10<sup>th</sup>, 2007 and the Advisory Action mailed on February 26<sup>th</sup>, 2008.

Applicant rather appears confused that an opening through one intermediate member could motivate one to form a whole through an equivalent intermediate member (the actual receiver of Parker). Therefore, all of applicant's arguments are directed to spurious issues of Parker and applicant's invention not having a seat/compression member which is irrelevant to the obviousness rejection set forth.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733